

Questions and Answers Regarding Directives 5000.2, 6420.2, and 10,010.1, Revision 1, and the Compliance Guidelines on *E. coli* O157:H7

Part I -- Purpose

The Agency is issuing this document to respond to questions from industry and Food Safety and Inspection Service (FSIS) personnel that have arisen concerning Directives [5000.2](#), [6420.2](#), and [10,010.1, Revision 1](#), and the guidance, entitled, "[Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities For *Escherichia coli* O157:H7.](#)" FSIS issued the directives on March 31, 2004, and the guidance on April 13, 2004. FSIS implemented Directive 5000.2 when it was issued and implemented Directives 6420.2 and 10,010.1, Revision 1, on May 17, 2004.

FSIS intends to issue additional documents to respond to other questions on these directives and the compliance guidelines, as the number of questions justifies a new issuance.

In the next year, FSIS intends to revise Directive 10,010.1, Revision 1, to incorporate information in the responses to questions below and responses to additional questions that may arise.

Part II – Risk-Based Sampling: Directive 10,010.1, Revision 1

As explained in Q&A #2 and #3 in Attachment 1 to the directive, FSIS intends to develop a more risk-based sampling program.

1. Question: If an establishment analyzes samples from 100% of raw beef products intended for grinding, and the grinding establishment communicates that information to its inspector, would FSIS sample and test these same products for *E. coli* O157:H7 after they are ground?

Response: Yes, the ground product would be subject to sampling and testing for *E. coli* O157:H7.

FSIS will collect information concerning establishments' production practices in order to implement a more risk-based sampling program. Under a risk-based sampling program, FSIS would sample product at establishments that analyze samples from 100% of raw beef products intended for grinding or that receive such products for grinding less frequently than the Agency would sample product at establishments that test less product or that receive product that has not been tested.

2. Question: The directive provides that FSIS will not collect raw ground beef product samples for *E. coli* O157:H7 testing at retail facilities that only repackage or regrind raw ground beef product previously ground at an official establishment, as long as the retail facility does not conduct any practices that would introduce *E. coli* O157:H7 in the product. Will FSIS collect raw ground beef product samples from official establishments

that only repackage or regrind product previously ground at another official establishment?

Response: Establishments that do not grind product and only portion such product into retail trays would not routinely be subject to sampling. In addition, once FSIS collects information concerning production practices, establishments that only regrind product previously ground at another establishment will likely be sampled at a very low frequency.

3. Question: Will establishments have an opportunity to review the frequency at which FSIS intends to sample raw ground beef product at an official establishment and to review the data that FSIS used to determine that frequency?

Response: FSIS is in the process of establishing a risk-based verification testing program for *E. coli* O157:H7 in official establishments that produce raw ground beef product. FSIS has not yet collected all the data necessary to implement a risk-based testing program. After FSIS has developed the risk-based testing program, FSIS will determine whether it will make the data used to determine its testing frequency at establishments producing raw ground beef product available on the FSIS web site or through other means. Certain data on FSIS' testing programs is available to the public upon request in accordance with the Freedom of Information Act.

Part III -- Products Subject to Sampling: Directive 10,010.1, Revision 1

The directive provides that raw ground beef products and the beef products that are used to produce raw ground beef products will be the focus of FSIS' verification sampling and testing program for *E. coli* O157:H7. Products that FSIS may sample are listed in Parts II and VI of the directive.

1. Question: The directive provides that if FSIS finds a raw ground beef product sample positive for *E. coli* O157:H7, FSIS may test product from suppliers. In this situation, will FSIS sample and test the same type of raw ground beef component that comprised the raw ground beef product sampled?

Response: FSIS is developing its sampling program for raw ground beef components and raw beef patty components, although it has only implemented it for imported raw ground beef components and raw beef patty components. In the future, FSIS will determine how best to instruct its domestic inspection program personnel concerning the sampling of these products in U.S. establishments. If the type of component that comprised the raw ground beef product found positive for *E. coli* O157:H7 is available at the supplier, FSIS may sample that type of component. However, if that type of component is not available at the supplier, FSIS may sample another component at the supplier.

2. Question: How will FSIS determine which establishments to sample? Will FSIS make this determination based on HACCP category (e.g., raw ground only)? If so, establishments that produce other non-intact raw products would not be identified. Will these establishments be sampled?

Response: The directive provides that establishments producing raw ground beef products will be sampled (see Part II of the directive for a list of raw ground beef products). In addition, establishments producing raw ground beef components or raw beef patty components may be sampled if FSIS finds ground product made from the supplying establishments' source materials positive for O157:H7 (see Part VI of the directive). The directive does not address sampling of non-intact raw beef products other than raw ground beef products and any non-intact components used to produce raw ground beef and beef patties (such as AMR product). In the future, FSIS intends to develop a random sampling and testing program for non-intact beef products other than ground beef, such as mechanically tenderized and injected steaks and roasts (see Q&A #1, in Attachment 1).

3. Question: Is there a difference between "chopped" beef and finely sliced beef? Would finely sliced beef be subject to FSIS sampling and testing.

Response: There is a standard of identity for "chopped beef" (9 CFR 319.15). Under the standard of identity, "chopped beef" is synonymous with "ground beef." The directive also states that raw "chopped" beef is a "raw ground beef product" (see Part II of the directive). The process of grinding or chopping is different from the process of finely slicing. Finely sliced beef would not be considered to be a raw ground beef product and, therefore, would not be included in FSIS' sampling program for raw ground beef products.

4. Question: What does the agency consider to be "trimmings?" Is stew meat or a misshaped portion that is diverted for further processing considered "trimmings?"

Response: Trimmings are an example of raw ground beef components or beef patty components (see Part VI of the directive). Boneless beef is also an example of product that may be subject to testing. If stew meat or a misshaped portion is intended for use in raw, non-intact beef product, FSIS would consider it to be trimmings or boneless beef that may be subject to sampling.

5. Question: Is ground beef product with added seasonings subject to FSIS *E. coli* O157:H7 sampling and testing?

6. Response: Yes. That product is considered ground or chopped beef.

Part IV--Defining the Sampled Lot: Directive 10,010.1, Revision 1

The directive does not define the "sampled lot."

1. Question: When FSIS samples a raw ground beef product, raw ground beef component or raw beef patty component for *E. coli* O157:H7, will the company's definition of a lot be considered or will FSIS determine the lot size?

Response: The company typically determines the lot when determining the amount of product to hold pending FSIS sample results. However, in the event of a positive, the FSIS recall committee may ask the company to recall product that the company did not

hold, if the recall committee determines that the company did not hold all the product that was implicated by the sample result.

In the event of a positive, FSIS generally determines the amount of product that should be recalled based on various factors, such as the control measures in place within the operation to limit potential contamination exposure of product that was produced from clean-up to clean-up. FSIS also considers the amount of carryover or rework from other production lots and any other factors that may link other production lots to the sampled product. The recall committee is responsible for evaluating all production factors and control measures, and then determines the scope of the recall.

2. Question: What would FSIS consider a “supportable basis” for defining a sampled lot? When FSIS samples raw ground beef product for *E. coli* O157:H7, should establishments hold all lots made from the same raw materials as the ground product that FSIS samples?

Response: Raw ground beef products processed from clean-up to clean-up could be considered a lot. This definition of a lot may be supportable if the lots processed during other times remain separate from the lot sampled.

However, in the October 7, 2002, [Federal Register](#) notice, FSIS cautioned that an establishment’s defined lot size does not relieve an establishment from its responsibility to consider whether there are connections between lots. For example, if multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for *E. coli* O157:H7, FSIS would expect the establishment to have a scientific basis that justifies why any raw ground product produced from those source materials should not be considered to be adulterated (67 FR 62333). Possible scenarios of lots being associated with a positive lot can be found in the Compliance Guidelines (page 5).

Part V--Implications of *E. coli* O157:H7 Positive Test Results and Information on Testing: Directive 10,010.1, Revision 1

The directive discusses the follow-up actions that FSIS takes after an FSIS sample tests positive for *E. coli* O157:H7. The directive also recognizes that many establishments test their raw beef products for *E. coli* O157:H7 and instructs inspection program personnel to verify that establishments take appropriate actions in response to positive findings.

In the Background section, the directive explains what FSIS considers to be a “presumptive positive” result and a “confirmed positive result.”

1. Question: Will the HACCP plan of an establishment that ships product be considered inadequate if the establishment’s test results indicate that a raw ground beef component is negative for *E. coli* O157:H7 but a receiving establishment subsequently tests the product and finds it presumptive positive or positive for *E. coli* O157:H7?

Response: In this situation, FSIS would not automatically consider the HACCP plan to be inadequate. However, in this situation, FSIS would expect the establishment that produced the raw ground beef component to conduct corrective actions and to attempt to determine the cause of the positive findings.

If the receiving establishment finds the product presumptive positive and intends to conduct confirmation testing, the establishment that produced the raw ground beef component can wait until the confirmation test results become available before taking any necessary corrective actions. If the confirmation test results indicate the product is negative for *E. coli* O157:H7, the establishment that produced and supplied the raw ground beef component would not need to conduct corrective actions.

2. Question: If FSIS or the establishment finds raw ground beef product positive for *E. coli* O157:H7, will all product at the establishment be kept on hold?

Response: If FSIS obtains a positive result, FSIS will conduct a HACCP 02. As part of the 02, FSIS will verify that the establishment implements corrective actions. FSIS will typically collect a follow-up sample after the establishment has completed its corrective actions.

Whether FSIS or the establishment finds product positive, the establishment is responsible for conducting corrective actions. Therefore, the establishment is responsible for ensuring that no product represented by the sample enters commerce. Not all product at the establishment would necessarily be represented by the positive sample.

3. Question: Will FSIS issue a noncompliance record based upon the results of an *E. coli* O157:H7 positive from an Agricultural Marketing Service (AMS) test result?

Response: Yes.

4. Question: If FSIS finds raw ground beef product positive for *E. coli* O157:H7, will suppliers be identified in the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS) as having supplied product that FSIS found positive for *E. coli* O157:H7 if the product came from several suppliers and none could be identified specifically?

Response: If records indicate that the supplier contributed to a raw ground beef product sample that FSIS confirmed positive for *E. coli* O157:H7, that supplier is entered into the STEPS system, even if there were multiple suppliers that contributed to the product.

5. Question: Has FSIS changed the definition of "confirmed positive?"

Response: The directive specifies the criteria for confirming a sample positive for *E. coli* O157:H7. FSIS' criteria for confirming a sample positive for *E. coli* O157:H7 have not changed since FSIS last revised its testing method for the pathogen.

6. Question: What are the differences between “potential” and “presumptive” test results? What type of test would “indicate the strong possibility that *E. coli* O157:H7 is present?”

Response: Potential: For FSIS testing, a potential positive for *E. coli* O157:H7 is that reacting to a screening test. FSIS methodology calls for an immunoassay screen (dipstick) after 24 hours incubation in Modified *E. coli* (MEC) Broth.

The directive does not discuss industry “potential” positive results. The directive only provides instructions to inspection program personnel concerning industry positive and presumptive positive results.

Presumptive: For FSIS testing, a presumptive positive for *E. coli* O157 is that reacting to the O157 somatic antiserum. This test and reaction indicates a “strong possibility that *E. coli* O157:H7 is present.”

For industry testing, test results that indicate a strong possibility that *E. coli* O157:H7 is present are considered presumptive positive results. Positive results of industry testing for *E. coli* O157:H7 using the BAX (trademark name) methodology would be considered presumptive positive results. If establishments use testing methodology other than BAX methodology, and inspection program personnel are not certain whether the establishment’s test results are presumptive or confirmed findings, FSIS will instruct inspection program personnel to contact the Technical Services Center (TSC) for assistance.

Part VI--FSIS’ Sampling Procedures: Directive 10,010.1, Revision 1

1. Question: The directive is silent on the issue of when an inspector is to draw a sample during the production day. Has the agency provided any guidance to its in-plant personnel?

Response: Directive 10,210.1, Amendment 3, addresses the issue of when an inspector is to draw a sample during the production day. This directive states that, “FSIS inspection program personnel may collect a scheduled MT03, MT04, MT05, or MT06 sample at **any** randomly selected day, shift and time within the sample collection timeframe on FSIS Form 10,210-3.” In the near future, Directive 10,210.1 will be revised and will contain new project numbers but very similar instructions.

2. Question: Some establishments ship fresh ground beef as it is ordered each day. Therefore, in order to hold the sampled lot, these establishments need at least a day’s notice of FSIS’ intent to sample. Will FSIS provide this advance notice to such establishments?

Response: Yes. As explained in Q&A # 9, in Attachment 1 to the directive, the establishment can request that the inspector notify the establishment the day before the inspector is to take a sample, so the establishment can adjust the production levels to

fill its orders but still hold the sampled lot. The Q&A states that the inspector should accommodate such a request. When the inspector notifies the establishment the day before he or she is to take the sample, the inspector may take the sample at any time during the following production day.

Part VII--Control of Positive Product: Directive 10,010.1, Revision 1

The directive provides instructions to inspection program personnel for verifying control of beef products that are presumptive positive or positive for *E. coli* O157:H7 (see Parts IV, A.; VI, D.; and VII, B.).

1. Question: Can presumptive positive or positive product be shipped through a distributor?

Response: Generally, presumptive positive or positive product may not be shipped through a distributor because the establishment that produced the product must maintain control of it during shipment. Ownership is typically passed once the distributor holds the product. However, there may be circumstances when an establishment can ship presumptive positive product or positive product through a distributor.

In order to ship presumptive positive or positive product through a distributor, the establishment that produced the product would have to do the following:

- 1) maintain control of the product while it is in transit (e.g., through company seals) or ensure such product moves under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);
- 2) maintain records identifying the official establishment, renderer, or landfill that received the product; and
- 3) maintain records that show that the product received proper disposition, including documentation evidencing proper disposal of the product from the official establishment where disposition occurred or from the renderer or landfill where disposition occurred (see Part VII, B. 2. of the directive).

2. Question: To document that raw beef that is presumptive positive or positive for *E. coli* O157:H7 received proper disposition, can the establishment that produced this product receive one general letter from a second establishment that has agreed to receive *E. coli* O157:H7 presumptive positive or positive raw beef product and cook it or conduct other further processing of such product? Or must the establishment that produced the *E. coli* O157:H7 presumptive positive or positive product receive a letter from the establishment where disposition occurred, following disposition of each lot of presumptive positive or positive product?

Response: Under 9 CFR 417.3, establishments' required corrective actions include ensuring that no product that is adulterated enters commerce. Under 9 CFR 417.5, establishments must document their corrective actions. Therefore, establishments must maintain records that show that presumptive positive or positive product produced at the

establishment received the proper disposition. A general letter from establishments that further process the presumptive positive or positive product indicating that any such product received under a contractual agreement will receive an adequate lethality treatment would not be sufficient. Rather, establishments should maintain specific records that show that each lot of presumptive positive or positive product they produced received proper disposition.

Part VIII--The October 7, 2002, *Federal Register* Notice

On October 7, 2002, FSIS published a notice requiring establishments that had not already reassessed their HACCP plans for raw beef products in light of relevant *E. coli* O157:H7 data to do so to determine whether *E. coli* O157:H7 contamination was reasonably likely to occur in their production process for raw beef products (67 FR 62329).

Question: Does the mark of inspection signify compliance with the October 7, 2002, *Federal Register* Notice requiring validated interventions designed to eliminate or reduce *E. coli* O157: H7 to undetectable levels?

Response: No. The October 7, 2002, *Federal Register* notice did not require validated interventions for *E. coli* O157:H7. Rather, it required that all establishments reassess their HACCP plans for raw beef products, based on relevant *E. coli* O157:H7 data, if they had not already done so.

Part IX--Retail Sampling: Directive 10,010.1, Revision 1

The directive provides instructions to program investigators for collecting samples of raw ground beef product at retail (see Part X of the directive).

1. Question: Under what circumstances would FSIS direct program investigators NOT to collect raw ground beef product at retail when the retail facility is grinding beef manufacturing trimmings and selling it as case-ready product?

Response: FSIS would consider specialty handled beef manufacturing trimmings (as described below), when ground at retail, the same as coarse ground product from official establishments. Therefore, FSIS would not collect samples of raw ground beef product made from these trimmings at retail facilities, provided that the retail facility does not conduct any practices that would introduce *E. coli* O157:H7 in the product (see Part X , A., 4. of the directive for examples of practices that may introduce *E. coli* O157:H7 in the product).

Specialty handled beef manufacturing trimmings generally are sub-primals that have undergone an antimicrobial treatment for *E. coli* O157:H7 as part of a HACCP plan, are trimmed to meet a specific lean to fat ratio, are cut into slices, are sampled for *E. coli* O157:H7 through the establishment's verification testing program, and are sealed in

bags for direct sale to a retail facility. As part of the design of its HACCP plan, the official establishment addresses the intended users of the specially handled beef manufacturing trimmings (i.e., the retail facilities) and maintains a mechanism for informing the retail facility about the need to control the product to prevent contamination with *E. coli* O157:H7.

The retail facility, in turn, opens the sealed bags of specially handled beef manufacturing trimmings and grinds the contents of the bags without mixing in other beef manufacturing trimmings. The retail facility also applies a label to the finished product that identifies the product similarly to the way other case-ready ground beef product made from coarse ground product that is further ground and repackaged at retail is identified.

FSIS will instruct inspection program personnel in the official establishment to notify the District Inspection Coordinator, via e-mail, that the establishment is preparing specially handled beef manufacturing trimmings for sale to retail. The District Inspection Coordinator will inform the District Manager regarding the potential need to have an Enforcement Analysis and Investigations Officer (EAIO) review the food safety system associated with the process and will ensure that the Office of Public Health Science is notified of production of such product, so that FSIS can include the specially handled beef manufacturing trimming in the FSIS verification testing program for *E. coli* O157:H7.

The District Manager also will share information about the establishment's program with the appropriate Office of Program Evaluation, Enforcement and Review (OPEER) Regional Manager, so that program investigators will not pull samples of ground product from retail facilities that grind specially handled beef manufacturing trimmings and that use appropriate grinding practices and controls.

2. Question: The directive discusses retail facilities grinding trim but does not discuss retail facilities grinding chuck roasts and other whole muscle cuts. If a retail facility grinds these products, would the ground product be subject to FSIS sampling?

Response: Yes, that product would be subject to FSIS sampling. One of the "raw ground beef components" in the directive is "boneless beef," which would include chuck roasts and other whole muscle cuts (see Part VI of the directive).

3. Question: Would it be an acceptable practice for a retail facility to have one grinder for regrinding product previously ground at official establishments and another grinder for grinding trim and other whole muscle cuts?

Response: Yes. FSIS would only sample the ground product from trim and whole muscle cuts, as long as the retail facility does not conduct any practices that would introduce *E. coli* O157:H7 in the product previously ground at official establishments.

4. Question: In the event of an FSIS positive test result from a sample collected from

a retail facility, would the clean-up to clean-up definition for the sampled lot still apply?

Response: In the event of a positive test result from product ground at retail, FSIS generally determines the amount of product that should be recalled based on such factors as the control measures in place within the operation to limit potential contamination exposure of product that was produced from clean-up to clean-up, carryover or rework from previous ground beef production lots, and any other factors that may link other production lots to the sampled product (see Q&A # 2 in Part IV of this document for more information on possible connections between lots). The recall committee is responsible for evaluating all production factors and control measures, and then determines the scope of the recall.

5. Question: If FSIS collects a sample from a retail facility that regrinds product that was previously ground at official establishments at the start of operations and then begins grinding trim later in the day's production, what is the definition of the sampled lot?

Response: As long as the retail facility does not conduct any practices that could introduce *E. coli* O157:H7 in the product previously ground at official establishments, FSIS would only sample ground product from the trim. Although the directive does not deal with this issue, the sampled lot would only include the product from trim, because product first ground at official establishments has been inspected and passed and is not subject to sampling. However, if the entire day's production is packaged, labeled and coded the same, the entire day's production may be subject to recall in the event of an FSIS positive finding, because there would be no means to distinguish the product that was only reground at retail from product that was produced from trim.

6. Question: Retail facilities often combine trim from multiple suppliers to produce raw ground beef product with specific fat and lean content throughout a day's production. When retail facilities use multiple suppliers throughout the day, they often cannot identify the specific suppliers for each ground product produced. Therefore, when FSIS samples the raw ground beef product and collects information on suppliers, retail facilities typically provide information for all the suppliers that they used for the day, rather than provide the specific suppliers for the sample collected. Is this practice acceptable?

Response: Yes. Although FSIS recommends that retail facilities track the specific suppliers used for the raw ground beef products they produce, FSIS understands that retail facilities combine trim from multiple suppliers throughout a day's production and that tracking the specific suppliers for each product throughout the day may not be practicable.

7. Question: Will FSIS notify retail facilities of negative *E. coli* O157:H7 results?

Response: Yes, FSIS will notify retail facilities of negative FSIS *E. coli* O157:H7 results if the retail facility calls the toll-free number that is provided to management of the retail

facility when a sample is collected.

8. Question: If FSIS collects a follow-up raw ground beef sample at retail in response to an FSIS *E. coli* O157:H7 positive result, will FSIS notify the retail facility before collecting the follow-up sample?

Response: Although this is not stated specifically in the directive, program investigators should make an effort to notify the retail facility the day before they collect the follow-up sample. If this is not possible, program investigators should try to get to the retail facility as close to the beginning of grinding operations as possible.

9. Question: How soon after an FSIS *E. coli* O157:H7 positive result will FSIS collect a follow-up sample at retail?

Response: In response to an FSIS positive result, FSIS will collect a follow-up sample at the retail facility as soon as feasible, depending on the program investigator's schedule and work assignments.

10. Question: If FSIS finds a sample positive for *E. coli* O157:H7 at a retail facility that was grinding trim at the time the sample was collected, and, as a result of the FSIS positive finding, the facility decides to discontinue grinding trim, will FSIS still collect a follow-up sample?

Response: If the retail facility is no longer grinding trim and is not conducting any practices that would introduce *E. coli* O157:H7 in the product, FSIS would not automatically collect a sample. However, in these circumstances, FSIS may pull a sample based on input from the program investigator.

11. Question: Will FSIS sample trim at retail facilities?

Response: No, the directive does not provide for sampling trim at retail facilities.

12. Question: If a retail facility does grind trim but is not grinding trim at the time that a program investigator arrives to collect a sample, will the program investigator ask the facility to begin grinding the trim?

Response: No, the program investigator will not collect the sample.

Part X--Import Sampling and Importers: Directive 10,010.1, Revision 1

The directive provides instructions to import inspection personnel for sampling raw ground beef product at import establishments (see Part XI).

1. Question: FSIS previously permitted the foreign government to draw and analyze the sample. Will this still be permitted?

Response: No. The Office of International Affairs (OIA) no longer permits foreign governments to test product for *E. coli* O157:H7 in lieu of FSIS testing at port-of entry. Under port-of-entry reinspection practice, FSIS will select a statistically representative sample of imported raw ground beef lots for an organoleptic exam and will sample about 1 in 12 of those for *E. coli* O157:H7. A positive finding at port-of-entry will result in the producing establishment being placed on intensified reinspection, and the establishment's next 15 lots will be sampled for *E. coli* O157:H7. In addition, if FSIS finds a sample of raw ground beef positive for *E. coli* O157:H7 at a U.S. grinder and the sole source of trim was a foreign plant, FSIS will conduct *E. coli* O157:H7 testing on the next 15 lots of trim from that establishment.

2. Question: Will raw ground beef products, raw ground beef components, or raw beef patty components labeled with an instructional statement (e.g., "for cooking only") be tested at port-of-entry?

Response: No. FSIS import inspectors will sample only products intended for use in finished, raw, non-intact product.

3. Question: Is presumptive positive or positive product eligible for importation to the U.S.?

Response: No. Foreign inspection services cannot provide health certificates for products that may be adulterated.

4. Question: Can suppliers in foreign countries demonstrate that *E. coli* O157:H7 is not a food safety hazard reasonably likely to occur in their operations, based on test data provided by the suppliers?

Response: FSIS has advised foreign governments that it expects establishments in exporting countries would initiate effective processing interventions to control for *E. coli* O157:H7 if their hazard analysis produces evidence that this pathogen is present in the beef food animal chain at any level of prevalence above zero. In addition, if an establishment has purchase specifications that require that incoming product has been treated to eliminate or reduce *E. coli* O157:H7 to an undetectable level, FSIS would expect that establishment to ensure that its purchase specifications are met in order for that establishment to determine that it does not need a separate critical control point (CCP) for the pathogen. FSIS would expect all products received according to the purchase specifications to have been treated to eliminate or reduce *E. coli* O157:H7 to an undetectable level. If the establishment has purchase specifications addressing *E. coli* O157:H7 and certain suppliers have not met the purchase specifications, because they have determined that *E. coli* O157:H7 is not a hazard reasonably likely to occur, FSIS would likely question the efficacy of the purchase specifications.

Part XI—Instructional and Disclaimer Statements: Directive 10,010.1, Revision 1

The directive includes verification activities for inspection program personnel to conduct at establishments that place instructional or disclaimer statements concerning *E. coli* O157:H7 on raw beef products and at establishments that receive raw beef products bearing these statements (see Part IX of the directive).

1. Question: Can beef manufacturing trimmings or ground beef be labeled with an instructional statement (e.g., “for cooking only”) if it has not been tested for *E. coli* O157:H7?

Response: Yes. The product is not required to be tested for O157:H7 to bear an instructional statement. Inspection program personnel are to verify that the use of any instructional statement is reflected in the establishment’s decisionmaking documents or hazard analysis. (See Part IX, C., 3 of the directive.) Q&A #17, in attachment 1 to the directive also provides information on how the placement of the instructional statement should be reflected in HACCP documents.

2. Question: Can beef manufacturing trimmings or ground beef be labeled with an instructional statement (e.g., “for cooking only”) if it is not presumptive positive for *E. coli* O157:H7?

Response: Yes. There is no requirement that establishments label presumptive positive product with an instructional statement. To apply labels bearing instructional statements to products, establishments must obtain sketch approval from the Labeling and Consumer Protection Staff (LCPS) and their use of the instructional statement must meet the other criteria in the directive.

3. Question: Can establishments send raw ground beef products, raw ground beef components, and raw beef patty components labeled with instructional or disclaimer statements addressing *E. coli* O157:H7 to a meat broker or distributor?

Response: Generally, establishments may not send such product to a broker or distributor. When the LCPS approves the use of instructional statements addressing *E. coli* O157:H7 on these products, LCPS specifies that such statements can only be used on products destined for official establishments that ensure these products receive adequate lethality treatment. Similarly, when LCPS approves the use of disclaimer labeling statements addressing *E. coli* O157:H7 on these products, LCPS specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plan. Brokers or distributors may not have sufficient knowledge concerning the production of and intended use of this product and may not have adequate controls to ensure that such product goes to an official establishment with an appropriate production process.

However, an establishment that places instructional or disclaimer statements addressing *E. coli* O157:H7 on raw beef products may be able to send such product to a broker or distributor if:

1) the establishment has an arrangement with the broker or distributor that ensures that product on which it places an instructional or disclaimer statement ultimately goes to an official establishment with an appropriate production process; and

2) the establishment has a means of documenting that a second official establishment ultimately received the product and processed the product appropriately.

4. Question: What verification activities do inspection program personnel conduct at establishments receiving raw ground beef products, raw ground beef components, or raw beef patty components with instructional or disclaimer statements?

Response: The directive instructs inspection program personnel to verify that establishments receiving such product—

- 1) have addressed the use of incoming product with disclaimer statements in their HACCP plan as if the product may be contaminated with *E. coli* O157:H7; and
- 2) are following any instructional statements on the incoming product.

5. Question: If an establishment receives product with instructional or disclaimer statements, does that establishment need to provide documentation to the supplier that the product has received a lethality treatment or has undergone proper disposal?

Response: Establishments receiving product with instructional or disclaimer statements are generally not required to provide documentation to the supplier that the product has received a lethality treatment or has undergone proper disposal.

If the supplier sends product bearing disclaimer or instructional statements to a broker or distributor (see Q&A # 3, in Part XI of this document for information on sending such product to a broker or distributor), the supplier, broker, or distributor may request that the establishment that further processes the product for distribution provide documentation showing that the product was processed appropriately.

If establishments receive product that is presumptive positive or positive for *E. coli* O157:H7 and that product bears an instructional statement, establishments should document receipt of such product, should maintain control of the product, and should address *E. coli* O157:H7 in their HACCP plan, so that the product will receive an adequate lethality treatment (see part VIII of the directive).

In addition, if the supplier produced presumptive positive or positive product, the supplier should maintain records documenting that the product received proper disposition. Therefore, the supplier will normally request documentation from the establishment where disposition occurred (see parts IV, A., 5., e. and VII, B., 2., e. of the directive).

6. Question: If a product has been labeled with an instructional statement (e.g. “for cooking only”), must the receiving establishment actually follow those instructions, and,

if so, according to what regulation?

Response: Yes. The receiving establishment should follow the instructional statement. The reason for this is that the producing establishment has determined that the instructional statement indicates the appropriate use of the product. To be able to place an instructional statement on a label, the instructional statement must be reflected in the establishment's decisionmaking documents or hazard analysis. At establishments that place instructional statements on labels, inspection program personnel verify that the use of instructional statements is reflected in the establishments' decisionmaking documents or hazard analyses. The establishment receiving such product must follow the instructional statement because the label indicates the appropriate use of the product. If the receiving establishment is not following the instructions, the receiving establishment's decisionmaking documents or hazard analysis would not appropriately address the use of the incoming product, because its decisionmaking documents or hazard analysis would not be consistent with the instructions from the supplier. Therefore, the receiving establishment would not meet the requirements of the HACCP regulations.

7. Question: If inspection program personnel find that an establishment receives a raw beef product bearing an instructional statement addressing *E. coli* O157:H7 and does not follow the instructions, would FSIS retain the product or request that the establishment recall any product in distribution?

Response: Not necessarily. FSIS would retain product or ask the establishment to recall product in these circumstances if—

- 1) the establishment's process may not be adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels; and
- 2) the product is not intended for further processing that would destroy the pathogen.

See Part IX. D. 3. of Directive 10,010.1, Revision 1.

8. Question: If inspection program personnel find that an establishment receives a raw beef product bearing a disclaimer statement addressing *E. coli* O157:H7 and its hazard analysis or decisionmaking documents do not address the use of the incoming product as if it were contaminated with *E. coli* O157:H7, would FSIS retain the product or request that the establishment recall any product in distribution?

Response: Not necessarily. As with establishments that do not follow instructional statements addressing *E. coli* O157:H7, FSIS would retain product or ask the establishment to recall product in these circumstances if—

- 1) the establishment's process may not be adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels; and

- 2) the product is not intended for further processing that would destroy the pathogen.

See Part IX. D. 3. of Directive 10,010.1, Revision 1.

9. Question: If the receiving establishment is NOT following the instructional statement but the product receives a lethality treatment adequate to eliminate or reduce *E. coli* O157:H7 to an undetectable level, are inspection program personnel to issue a Noncompliance Record (NR)?

Response: Yes, inspection program personnel would issue the receiving establishment an NR. The receiving establishment's decisionmaking documents or hazard analysis would not appropriately address the use of the incoming product, because its decisionmaking documents or hazard analysis would not be consistent with the instructions from the suppliers (see Part IX, D., 2 of the directive and Q&A # 19 in Attachment 1 to the directive).

10. Question: If an establishment has obtained sketch approval for use of labeling bearing an instructional or disclaimer statement addressing *E. coli* O157:H7 on one particular raw ground beef product, raw ground beef component, or raw beef patty component, and the establishment wishes to use the statement on labeling of another product, is the establishment required to submit the labeling to FSIS for sketch approval a second time?

Response: Not necessarily. Under 9 CFR 317.5(b)(9), labeling may be generically approved if LCPS previously approved it as sketch labeling and the final labeling was prepared without modification or with only certain modifications. (See 9 CFR 317.5(b)(9)(i)-(xxiv) for allowable modifications). Therefore, if the establishment has received sketch approval for labeling bearing instructional or disclaimer statements on one particular raw ground beef product, raw ground beef component, or raw beef patty component, it may use the labeling on any other raw ground beef products, raw ground beef components, and raw beef patty components that it produces, as long as the establishment makes no modifications or only certain allowed modifications to the labeling.

11. Question: If LCPS approved establishments' sketch labeling bearing instructional or disclaimer statements addressing *E. coli* O157:H7 for use on raw ground beef products, raw ground beef components, or raw beef patty components before issuance of Directive 10,010.1, Revision 1, are establishments required to resubmit this sketch labeling to LCPS?

Response: An establishment should check its labeling records to determine the date that it received sketch approval for labeling bearing an instructional or disclaimer statement addressing *E. coli* O157:H7. If that date is earlier than March 31, 2004, the date the directive was issued, the establishment should resubmit the sketch labeling to LCPS to ensure that such labeling uses the instructional or disclaimer statement appropriately.

12. Question: Can warehouses that receive special services from FSIS under 9 CFR 350 repackage raw ground beef products, raw ground beef components, or raw beef patty components and apply labels that bear instructional or disclaimer statements addressing *E. coli* O157:H7 to the repackaged product, if the product's original package did not bear an instructional or disclaimer statement?

Response: No. Directive 10,010.1, Revision 1, instructs inspection program personnel to verify that establishments that apply these labels to raw beef product address the use of these labels and address *E. coli* O157:H7 appropriately in their HACCP documents and HACCP plan. Also, FSIS approves the use of labels bearing these statements only on product destined for official establishments. Warehouses cannot apply labeling bearing these instructional or disclaimer statements to product that does not bear these statements because warehouses are not required to have HACCP plans and because warehouses will not have sufficient knowledge concerning the production of the product or the product's ultimate destination to ensure that the labeling statements are used appropriately.

13. Question: Can product produced and packaged for use in the National School Lunch Program bear cooking instructions?

Response: Yes. LCPS will work with AMS and the Food and Nutrition Service to approve acceptable labeling with cooking instructions that can be used on product sent to institutions rather than official establishments.

Part XII--Compliance Guidelines

On April 13, 2004, FSIS issued guidance entitled, "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia Coli* O157:H7." Below, FSIS responds to numerous questions that have arisen concerning the guidelines. After completion of the series of FSIS' *E. coli* O157:H7 workshops in September 2004, FSIS intends to issue revised compliance guidelines that reflect the responses below and responses to other questions that arise during the workshops.

1. Question: The compliance guidelines state that, with regard to purchase specifications, a single annual letter from a supplier or photocopies of the same information is not enough supporting documentation and the documentation should accompany each shipment. Must documentation from the supplier regarding its intervention and testing accompany each shipment?

Response: An establishment's purchase specifications include conditions under which it will accept a supplier's product. An establishment should develop purchase specifications that it can use to discern an acceptable lot of raw beef product from one that is not acceptable. The establishment needs to ensure that those specifications are being met by developing and implementing on-going verification upon receipt of the product. If one of the criteria used for verification is receipt of a letter from the supplier,

the letter should state specifically how the supplier meets the purchase specifications and include some sort of feedback mechanism to notify the receiving establishment if the conditions changed at the supplier (e.g., during the higher prevalence season, the supplier may implement enhanced intervention and verification activity to further ensure that *E. coli* O157:H7 is eliminated, prevented, or reduced to an acceptable level). The Compliance Guidelines discussed some examples of conditions that a receiving establishment can include in its purchase specifications. Examples discussed include: 1) documentation of supplier's intervention methods and on-going verification of their effectiveness on file at the receiving establishment; 2) on-going communication, with records to support these communications, between supplying and receiving establishments on the effectiveness of the supplier's intervention methods in addressing *E. coli* O157:H7; and 3) a letter or memo from the supplier accompanying each shipment regarding test results.

Example # 3 provides that test results should accompany each shipment; therefore, an annual letter or a photocopy would not be enough supporting documentation. For this example, a letter from the supplier stating that all lots shipped have tested negative for *E. coli* O157:H7 should accompany the shipment to serve as supporting documentation that the meat has tested negative for the pathogen. If the establishment's conditions for receipt of product in the purchase specifications were changed to state that on a weekly, monthly, or quarterly basis, the supplier will provide a letter of affirmation to state that the supplier continues to conduct *E. coli* O157:H7 verification testing on each lot shipped to the receiver and will not release the shipment to the receiver until the test result is final and is negative for *E. coli* O157:H7, then a less frequent receipt of documentation is appropriate. However, if the purchase specifications do not require verification test results with each shipment, the receiving establishment should require its suppliers to provide evidence that the shipment has been adequately controlled to prevent, eliminate, or reduce the hazard (e.g., through enhanced verification testing by the supplier).

2. Question: In the compliance guidelines, is it correct that FSIS recognizes that an establishment can adopt a critical control point for testing?

Response: Q&A #5, in Attachment 1 to Directive 10,010.1, Revision 1, explains that in certain circumstances, a CCP for disposition based on finished product *E. coli* O157:H7 testing may be appropriate. The compliance guidelines address when a CCP for testing is appropriate, consistent with Q and A #5 in Attachment 1 to the directive.

3. Question: The compliance guidelines recommend that an establishment conduct finished product testing using FSIS methods or methods that are equivalent. The guidelines also explain that to conduct testing that is equivalent to the FSIS method: 1) the sample test portion (analytical unit) must equal at least 325 grams, analyzed as individual sub-samples having a maximum weight of 75 grams; and 2) the establishment must have evidence that demonstrates the method is equal to or greater in sensitivity than the current FSIS method. Does this recommendation apply to finished ground beef product testing only?

Response: At the present time, FSIS' *E. coli* O157:H7 testing methodology only applies to raw, comminuted beef products. Thus, the recommendation in the guidelines relates to raw ground beef and those raw beef components that are in a comminuted form.

4. Question: To follow the recommendations in the guidelines, must an establishment conducting its own testing analyze five sub-samples per 325 gram sample?

Response: As noted above, the guidelines explain that to conduct testing that is equivalent to the FSIS method: 1) the sample test portion (analytical unit) must equal at least 325 grams, analyzed as individual sub-samples having a maximum weight of 75 grams; and 2) the establishment must have evidence that demonstrates the method is equal to or greater in sensitivity than the current FSIS method.

If establishments want to follow the recommendation in the guidelines that they use FSIS testing methods or methods that are equal to or better in sensitivity than FSIS' methods, their testing would have to meet both criteria above.

Although FSIS is recommending that establishments conduct testing for *E. coli* O157:H7 using FSIS testing methods or methods that are equal to or better in sensitivity, FSIS is not requiring this testing. Rather, establishments are required to maintain documents supporting the adequacy of their testing program.

5. Question: The guidelines indicate that a supplier should notify its customers when the supplier's interventions are not properly implemented or found not to be effective. Would this require a supplier to notify all its customers whenever it has a problem with its interventions or whenever a single lot of trim or raw ground beef product tests positive for *E. coli* O157:H7, even if the problem with the intervention or the positive result did not affect a particular shipment to the customer?

Response: If a supplier's interventions are not properly implemented, are found not to be effective, or the establishment produces raw beef product that tests positive for *E. coli* O157:H7, the supplier must take corrective actions. To ensure that no product that is injurious to health or otherwise adulterated enters commerce, the supplying establishment should inform the establishments receiving affected product if its interventions used for this product were not properly implemented or found not to be effective or if product from lots sent to receiving establishments were found positive for *E. coli* O157:H7. If this supplier sent raw beef product to establishments from lots that were not found *E. coli* O157:H7 positive and that underwent effective interventions, the supplier would not need to notify those receiving establishments.

6. Question: The compliance guidelines state that a grinding establishment with purchase specifications should receive documentation from the supplier stating that a validated intervention is being used, and that the intervention is operating effectively as shown by negative tests for the pathogen during verification testing. What frequency of

verification testing by the supplying establishment would the agency consider acceptable to demonstrate effectiveness of the interventions? Would the agency consider quarterly testing by a third-party laboratory, with communication of results to the grinding establishment, sufficient?

Response: It is probable that, despite the ongoing processing interventions for controlling *E. coli* O157:H7, some samples of raw materials may test positive for *E. coli* O157:H7. These positives may be random events caused by common cause variation, or may have an identifiable, assignable cause that can be acted upon as part of corrective actions. Verification testing must occur at a frequency to help establish the difference between common cause and assignable cause variation in the testing results associated with raw materials destined for grinding. Through this statistical analysis, the establishment will be able to justify when follow-up actions are appropriate and sensible.

Both the supplier and the grinder are required to maintain documents supporting the monitoring and verification procedures the establishment selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Therefore, these establishments are required to maintain documents supporting the adequacy of their testing programs. If the supplier has effective interventions for *E. coli* O157:H7; conducts a rigorous verification testing program that provides a high level of confidence that if the organism were present, it would be found in all production lots at a definable level; and shares on-going verification records with the grinder, the grinder would be able to support less extensive *E. coli* O157:H7 verification testing than that conducted by the supplier.

7. Question: The compliance guidelines address negative and positive results for *E. coli* O157: H7. However the guidelines do not indicate whether these results are from a screening test or a confirmation procedure.

Response: If establishments that test their own products do not confirm presumptive positive results (results that indicate the strong possibility that *E. coli* O157:H7 is present), FSIS will consider these presumptive positive products as positive. FSIS will consider industry presumptive negative results as negative.

Part XIII—Directive 6420.2

1. Question: Zero tolerance does not apply to carcasses and parts that are sent to the vet rail. In that case, who has responsibility for ensuring that carcasses and parts sent to the vet rail are free of fecal or ingesta contamination before they are released back into production?

Response: This question refers to p. 3 II., A., 1., b. of the directive. The intent of this section was to ensure that the veterinarian has all tissues available in order to make a disposition. It is still the plant's responsibility to prevent and remove fecal, ingesta, or milk contamination. Establishments may work out logistics of doing this with local

inspection program personnel.

2. Question: If the establishment does not have a critical control point (CCP) for head meat and supports that decision in its HACCP plan, must the plant put one in place?

Response: Under 9 CFR 417, a HACCP plan must include, as appropriate, critical control points that are designed to control identified food safety hazards (417.2 (C)(2)). Because fecal material is a vehicle for pathogens, and because virtually all slaughter establishments recognize that contamination of meat by pathogenic microorganisms from fecal material, ingesta or milk is a food safety hazard that is reasonably likely to occur in the slaughter production process, slaughter establishments should have adopted controls (in their HACCP plans, Sanitation SOPs, or other prerequisite programs) that they can demonstrate are effective in reducing the occurrence of pathogens, including controls that prevent contamination of carcasses with fecal contamination, ingesta and milk.

3. Question: Inspection program personnel have been directed to sample the same amount of head meat that an establishment has listed in its monitoring procedure for the head meat CCP. What are inspectors directed to do if the establishment does not have a CCP for head meat?

Response: As explained in the response to the preceding question, slaughter establishments should have controls (in their HACCP plans, Sanitation SOPs, or other prerequisite programs) that they can demonstrate are effective in reducing the occurrence of pathogens, including controls that prevent contamination of carcasses, head, cheek, and weasand meat. Establishments should monitor their controls to ensure that they are functioning properly. Inspectors will take the same sample size as the plant does for its monitoring procedures.

4. Question: If an establishment does not sell weasand meat that is intended for grinding, must it still comply with the provisions in Directive 6420.2 for zero tolerance verification for weasand meat?

Response: Depending on final use of product, through the hazard analysis, a plant may make determinations that there is not a hazard reasonably likely to occur. For example, if the establishment produces weasand meat destined for inedible use, the introduction of pathogens from fecal contamination, milk, or ingesta would not be a hazard reasonably likely to occur.

5. Question: The HACCP guidebook for the preparation of HACCP plans instructs establishments to set up continuous monitoring where feasible. In-depth verification (IDV) teams are directed to ensure that establishments have done so. Have inspectors been instructed regarding what to do if the establishment has not set up continuous monitoring of head meat (e.g., continuous online inspection during production)?

Response: Plants need to support monitoring frequencies as per 417.5(a)(2). The Agency has not required continuous monitoring for carcass zero tolerance; in fact, FSIS does not know how that would be accomplished.

6. Question: When an establishment begins producing a new product, the agency gives 90 days for validation of the HACCP plan for the product. Why has the agency only provided one month for a plant to set up and validate a new CCP for weasand meat, and provide supporting documentation for all of the decisions made, procedures written, and frequencies set up?

Response: Establishments should reassess HACCP plans any time there is new information and determine whether CCPs are added or deleted. Additionally, supporting documentation for the validation of the critical limit of the CCP for zero tolerance would be the regulatory requirement.

7. Question: In the event of a finding of fecal material, milk or ingesta on livestock carcasses at or immediately after the final rail, a finding of feces, ingesta, or milk on head meat, cheek meat, or weasand meat, or a finding of fecal material on poultry carcasses entering the chill tank, how much product is considered contaminated?

Response: All product that was produced after the product that was represented by the last acceptable monitoring check may be contaminated; however, if the establishment can determine when the contamination occurred, and has evidence to support that determination, only product produced after contamination occurred would be considered potentially contaminated.

8. Question: What actions should the establishment take if inspection program personnel are not following the directive, but the establishment does not have a documented noncompliance to appeal? For example, what actions should the establishment take if the establishment is not appealing a noncompliance, but inspectors are doing verification checks on more carcasses than are listed in the directive or are using the establishment's HACCP monitoring method for carcass verification checks, rather than the method used by the final rail inspector?

Response: These types of concerns should be addressed through the supervisory chain (that is, first through the Inspector in Charge (IIC), then through the Front-Line Supervisor, and then through the District Office).

9. Question: Will FSIS verification procedures be the same for both HACCP-Based Inspection Models Project (HIMP) plants and non-HIMP plants?

Response: Yes they are the same because the current HIMP instructions (HIMP Draft Market Hogs) say to follow the current directive (now 6420.2). (The Agency does need to update the draft to say 6420.2 instead of 6420.1.)

10. Question: Under the market hog HIMP draft, fecal contamination of viscera is an other consumer protection concern (OCP-2), subject to performance standards. Would a non-compliance record be issued only if the establishment failed the performance standards?

Response: FSIS will notify the IICs at HIMP plants that FSIS verification procedures in Directive 6420.2 apply to HIMP plants.

11. Question: Does the directive apply to organs? There is a reference in the directive to 9 CFR 310.18 (a), which states, “Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt or foreign matter” Will compliance activities include the need for a CCP to control fecal material on organs?

Response: An establishment does need to consider fecal contamination of organs in its hazard analysis; however, the directive does not include verification activities addressing organs.

12. Question: Should beef market heads be subject to additional off-line verification activities for zero tolerance compliance?

Response: Head meat is subject to zero tolerance. If beef market heads are attached to the carcass, there would be no reason for FSIS to conduct a separate verification for the head. If heads have been separated from the carcasses at the time of post-mortem inspection, FSIS will conduct inspection of the heads off-line (probably at harvesting or packing). FSIS will not inspect the heads twice, unless there is a special reason to do so.

13. Question: What is FSIS’ expectation for producers of pork cheek or head meat that is intended for use as an ingredient in a processed meat items (e.g., sausage)? Would the agency consider it necessary for the establishment to have a CCP addressing fecal contamination?

Response: The regulations prohibit fecal contamination of meat products. Therefore, establishments slaughtering livestock intended for edible products, need to address the issue of fecal contamination on those products in their manufacturing process. Fecal material may contain pathogens. Therefore, fecal contamination must be addressed through Sanitation SOPs, other prerequisite programs, or HACCP. If establishments do not address fecal contamination through an effective written process control (HACCP, Sanitation SOP, or other written prerequisite program), FSIS may assign an EIAO to the establishment to conduct a comprehensive food safety assessment of the establishment’s food safety systems.

Part XIV -- Directive 5000.2: Review of Establishment Data By Inspection Program Personnel

1. Question: The directive states that inspection program personnel “are to be aware of all monitoring and all food safety testing conducted by the establishment.” How will this be accomplished, especially given that such programs may change over time?

Response: FSIS personnel have been trained that they need to develop a thorough knowledge of the establishment’s HACCP plan, Sanitation SOP, and any prerequisite programs referenced in the hazard analysis. They will be reviewing the establishment’s plans on an on-going basis to determine what changes are made, so that they are able to perform verification tasks.

2. Question: FSIS clearly distinguishes Sanitation SOPs from other sanitation requirements, through separate sections in the regulations and through separate inspection system activities. Does this indicate that FSIS considers sanitary conditions of non-food contact areas to be different from sanitary conditions of food contact surfaces? Is it appropriate for an establishment to use the same logic to conclude that non-food contact surface microbial results are not food safety related and do not need to be shared with inspection program personnel?

Response: All test results used in making food safety decisions must be available to FSIS personnel for review. This may include non-food contact surface safety testing, if it affects food safety decisions.

3. Question: How does FSIS view testing of non-contact surfaces and finished product for generic microbes such as APC, coliforms and *E. coli*? These data are not used to make HACCP decisions. Does the agency consider these data to be related to food safety or to shelf life and quality?

Response: Generally, all such test results have food safety impact and must be available to FSIS personnel for review. FSIS would question why the results of any testing for pathogens conducted to meet purchase specifications or for other purposes would not affect the hazard analysis. If non-pathogen test results are used to ensure that the production process controls the overall level of microbes in the product, these test results may also affect the hazard analysis, because the production process may be modified because of levels of non-pathogens. If purchase specifications call for testing of non-pathogens and the results are for information purposes only, those results would not affect the hazard analysis and would not generally be available to FSIS. However, if the specifications require that non-pathogens not exceed certain levels, those test results could affect the process and the hazard analysis and would be available to FSIS.

4. Question: Does the agency consider pre-operational microbiological test results to be related to food safety and subject to FSIS records review? What about GMP monitoring and pest control monitoring records?

Response: Yes. These test results must be available for FSIS review. Pest control monitoring records, if available, must be reviewed as part of the 06D pest control

procedure for inspectors. GMP monitoring is usually referenced in the HACCP plan as a pre-requisite program or a justification for not having a CCP. As such, these results must be reviewed by FSIS on a regular basis.

5. Question: Are establishments expected to provide results weekly or simply in response to requests by inspection program personnel?

Response: Establishments should be prepared to provide the results to FSIS inspection program personnel, and to discuss the significance of those results, at the weekly meeting.

6. Question: Who decides what testing or tests are related to food safety and therefore, must be available for record review? Is this the responsibility of the establishment or FSIS?

Response: Establishments decide what type and frequency of testing is necessary to support the decisions made in the hazard analysis. Thus, the establishment decides which testing programs are necessary to ensure food safety and which testing programs are unrelated to food safety and therefore not subject to review by FSIS. However, the establishment would have to explain to inspection program personnel why certain test records do not affect the hazard analysis. If an inspector learns of a testing program and questions whether it should be included in the hazard analysis, the inspector should contact the TSC for guidance.